

## **Remarks**

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

### ***Status of All of the Claims***

Below is the status of the claims in this application.

1. Claim(s) pending: 33-36, 38-42, and 48-63.
2. Claim(s) canceled: 1-32, 37, and 43-47.
3. Claim(s) added: None.
4. Claims withdrawn from consideration but not canceled: 35, 36, 42, 48, and 57.

It is believed that the above-identified new and amended claims are supported by the application as originally filed. For example, support for these claims can be at least found at pages \_\_\_\_ of the specification and FIGS. \_\_\_\_ of the drawings.

### ***Claim Informalities***

Claims 55, 49, and 58 have been amended to correct the informalities cited in items 5 and 7 of the Office Action. No new matter has been added through these amendments.

### ***Claim Objections***

In item 4, the language in claims 37, 50-52, and 59-61 was “objected to as being ambiguous and may render the claims indefinite because as claimed it is unclear how or what structure is responsible for the claimed hydrophobicity.” The Applicant respectfully traverses, because it is submitted that one of ordinary skill in the art, after reading the claims and specification, would understand the metes and bounds of the above-mentioned claims. As stated in §2173.02 of the MPEP, “[t]he examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.” Furthermore, “definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention

was made.” MPEP §2173.02. In other words, an Examiner “should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.” MPEP §2173.02. It appears that the Office Action is unnecessarily requiring the incorporation of additional features into the claims to suit a particular taste without explaining how or why one of ordinary skill would not reasonably recognize the metes and bounds of the claims.

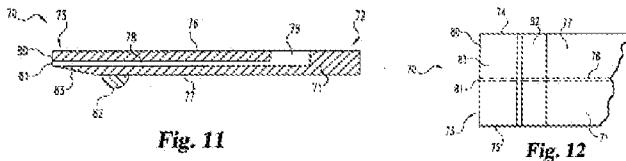
After reading the specification, one of ordinary skill in the art would clearly understand the metes and bounds of these claims. For example, page 9, lines 6-11 of the specification states:

The surface of the sealing member may be provided to be hydrophobic in various known ways, all of which are intended to be encompassed by the present invention. For example, the sealing member may be formed from a hydrophobic material, or may be provided with a hydrophobic coating. In addition, certain hydrophilic materials can be treated to be made hydrophobic in accordance with known techniques.

As should be recognized, one skilled in the art would easily understand and recognize that reciting for example “the sealing member has a surface that is hydrophobic” (claim 40) is specifying a property of the surface of the sealing member; namely, that the surface of the sealing member is hydrophobic. One skilled in the art would clearly understand that this hydrophobic property can occur in several ways, such as via the material used, coating, and/or treatment. Thus, one skilled in the art would clearly understand the metes and bounds of the claims.

### ***Technological Overview***

The present application describes and illustrates several unique test strip features that promote fluid collection. During fluid collection, test strips are typically positioned against the skin or are held slightly above the skin, at a location that positions the fluid inlet of the test strip adjacent to the drop of blood or other body fluid on the skin. However, the gap between the skin and the test strip tends to form a temporary capillary passageway that draw blood into the gap beneath the test strip, which in turn reduces the volume of body fluid available for testing.



**Fig. 11**

**Fig. 12**

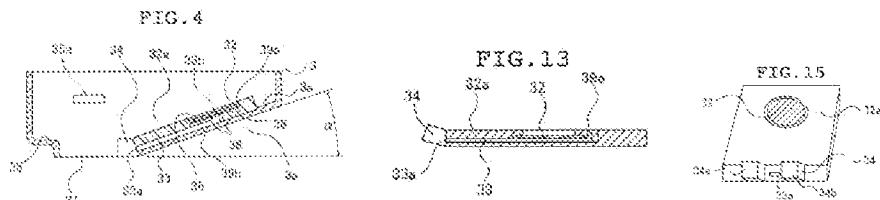
The test strips described and illustrated in the present application address these issues by incorporating several unique features. Looking at the embodiment illustrated in FIGS. 11 and 12 above, the test strip (70) includes a sampling passageway (78) that transfers body fluid from an inlet opening (81) at an end edge (80) of the test strip (70) to a test region (79) where the fluid sample is analyzed. Under the inlet opening (81), a sealing member (82) is located on the bottom surface (77) of the test strip edge (80) at a position to contact and seal with the skin during fluid collection. The sealing member (82) is aligned such that body fluid present near the inlet opening (81) is blocked from passing under the test strip (70). To assure a fluid tight seal with the skin, the sealing member (82) is made of material that is deformable when pressed against the skin. The sealing member (82) in FIG. 12 extends from the first edge (74) to the second edge (75) (i.e., edge-to-edge) so as to prevent the body fluid flowing around or bypassing the sealing member (82).

In addition, the test strip (70) is configured to prevent capillary action in the gap between the skin and the test strip (70) from ever occurring in the first place. Generally speaking, capillary action is based in part on the adhesive force between the body fluid and the bottom surface (77) of the test strip (70). The test strip (70) is designed to prevent undesirable capillary action underneath the test strip (70) from occurring in the first place by including a recessed surface (83) that tapers away from the inlet opening (81) to the bottom surface (77). The recessed surface (83) provides a space for the drop of fluid so that the chance of the fluid contacting the bottom surface (77) of the test strip (70) is reduced. To further prevent wicking toward the underside of the test strip (70), the recessed surface (83) and/or the bottom surface (77) are hydrophobic so as to inhibit any adhesion of the sample to the surfaces (77, 83). The sealing member (82) as well can be hydrophobic so as to resist wicking of body fluid in any gaps between the sealing member (82) and the skin's surface. By preventing the fluid sample from wicking or otherwise flowing away from the inlet opening (81), the above-mentioned features ensure that larger volumes of body fluid samples are available for collection and testing.

### ***Independent Claims 33***

Independent claim 33 has been amended to incorporate the features of dependent claim 37, and accordingly, dependent claim 37 has been canceled. In item 10 of the Office Action, claim 37 was “rejected under 35 U.S.C. 102(e) as being anticipated by Nishikawa et al. (US 6,315,738 B1, hereinafter Nishikawa).” However, as should be apparent, Nishikawa fails to disclose all of the features recited in claim 33, such as “wherein the sealing member has a surface that is hydrophobic.”

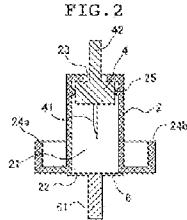
As shown in FIGS. 4, 13, and 15 below, Nishikawa concerns a body fluid-monitoring system that has a test strip (32) with body fluid guides (34) for guiding body fluid into the body fluid inlet (33a) of the test strip (32).



In item 11 of the Office Action, it was purported that the body guides (34a-d) corresponded to the recited sealing member, and in item 13, it was alleged that “Nishikawa discloses a sampling system, wherein the sealing member has a surface comprised of a hydrophobic material (column 11 lines 33-36) (the known hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).” However, Nishikawa at column 11, lines 33-36 (reproduced below, emphasis added) clearly teaches exactly the opposite. That is, the body fluid guides (34) should be hydrophilic and not hydrophobic.

The body fluid guide 34 may be formed from the same material as the second housing 3 or the test strip housing 32a, and the body fluid guide 34 is preferably imparted with hydrophilicity as in the case of the flow path 33.

The passage identified in the Office Action as listing known hydrophobic polymers, column 8, line 66 – column 9, line 7, in reality identified polymers used for the first housing and not the fluid guides (34) (see, FIG. 2 below).



Given that Nishikawa fails to disclose “wherein the sealing member has a surface that is hydrophobic” as is recited in claim 33, it does not anticipate claim 33. Moreover, such a feature would not be obvious in view of Nishikawa. If the fluid guides (34) were made hydrophobic (instead of hydrophilic), the intended function of the fluid guides (34) would be destroyed because the fluid guides (34) would inhibit fluid flow to the body fluid inlet (33a). For these and other reasons, independent claim 33 and its dependent claims are allowable over the references of record.

#### ***Claim 33's Dependent Claims***

In addition to the reasons given above for the allowability of independent claim 33, other reasons support the allowance of its dependent claims.

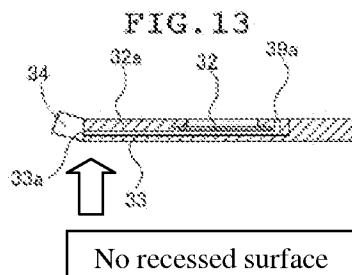
For example, Nishikawa fails to disclose “wherein the sealing member is deformable upon pressing against the skin” as is recited in dependent claim 38. As noted before, having the sealing member being deformable ensures a fluid tight seal with the skin. Nishikawa never mentions that the fluid guides (34) are deformable when pressed against the skin, and all the drawings in Nishikawa indicate that the fluid guides (34) are rigid in nature.

As another example, Nishikawa fails to “wherein the test strip has a recessed surface extending between the inlet opening and the bottom surface” as is recited in claim 39. As mentioned in the background section above, the recessed surface inhibits wicking under the test strip. As will be explained again below, in light of the specification, especially the definition on page 12, no one of ordinary skill in the art would have reasonably considered the bottom surface (3a) of the housing (3) to be the recited recessed surface.

### ***Independent Claim 40***

In item 10 of the Office Action, claim 37 was “rejected under 35 U.S.C. 102(e) as being anticipated by Nishikawa et al. (US 6,315,738 B1, hereinafter Nishikawa).”

Independent claim 40 has been amended to further clarify the recited recessed surface. In particular, claim 40 now recites “wherein the recessed surface tapers away from the inlet opening to the bottom surface.” As can be seen in the marked-up version of FIG. 13 below, the test strip (32) in Nishikawa does not have a recessed surface that tapers from the body fluid inlet (33a) to the bottom surface (3a) (see, FIG. 4 above).



In the Office Action, it was alleged that the test strip support (38) in Nishikawa corresponded to the recited bottom surface. However, even broadly construed, no one of ordinary skill in the art would have reasonably concluded that the test strip support (38) in Nishikawa corresponded to the recited bottom surface. Instead, one skilled in the art would have likely found the bottom surface (3a) as corresponding to the recited bottom surface. It is well settled that “[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999),” MPEP §2111. Looking at FIG. 13 above, there is no tapered surface between the body fluid inlet (33a) and the bottom surface (3a). Moreover, even based on the unreasonable interpretation provided in the Office Action (purely for the sake of argument), the test strip (32) in Nishikawa clearly does not have any type of surface that tapers from the body fluid inlet (33a) to the test strip support (38). For these and other reasons, it is submitted that claim 40 and its dependent claims are allowable over the references of record.

### ***Claim 40's Dependent Claims***

In addition to the reasons given above for the allowability of independent claim 40, other reasons support the allowance of its dependent claims.

For example, Nishikawa fails to disclose “at least a portion of the top surface is hydrophobic to resist flow of the body fluid along the top surface” as is recited in dependent claim 59. As described at column 10, lines 44-57, Nishikawa clearly teaches that the test strip housing (32a) should be hydrophilic and not hydrophobic. Consequently, Nishikawa never discloses a top surface that is hydrophobic.

As another example, Nishikawa does not disclose “wherein at least a portion of the bottom surface is hydrophobic” as is recited in dependent claim 60. Again, Nishikawa only teaches that the test strip housing (32a) should be hydrophilic. Nishikawa never discloses a bottom surface that is hydrophobic.

In still yet another example, Nishikawa fails to disclose “wherein the recessed surface is hydrophobic” as is recited in dependent claim 61. Nishikawa only discloses a hydrophilic test strip housing (32a), and it never discloses a recessed surface that is hydrophobic.

*Conclusion*

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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